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Primary Stenting for Complex Atherosclerotic Plaques in Aortic and Iliac Stenoses

Baran Önal, Erhan T. Ilgit, Cem Yücel, Erdal Özbek, Murat Vural, Sergin Akpek

Department of Radiology, School of Medicine, Gazi University, Beşevler, 06510 Ankara, Turkey

Abstract

Purpose: To evaluate the efficacy of primary stenting for complex atherosclerotic plaques in aortic and iliac stenoses that are not amenable to balloon angioplasty alone.

Methods: Nineteen patients with complex atherosclerotic plaques were treated with a Palmaz stent ($n = 19$), Wallstent ($n = 1$), Strecker stent ($n = 1$), or Memotherm stent ($n = 1$). A total of 22 stenoses presenting with complex plaque morphology including ulcerated plaques, ulcerated plaques with focal aneurysms, plaques with heavy calcification, severely eccentric plaques, plaques with overhanging edge, and plaques with spontaneous dissection were stented. The lesions were in the aorta ($n = 1$), common iliac artery ($n = 19$), or external iliac artery ($n = 2$).

Results: Immediate angiography after stent placement revealed restoration of patency of the stented segment. Focal aneurysms and ulcerated areas were occluded in the follow-up angiographies obtained 4–12 weeks after the procedure. In one case with poor distal runoff and multiple complex lesions of the iliac artery, subacute occlusion occurred. Clinical and angiographic follow-up (3–46 months) revealed patency of all other stented segments.

Conclusion: Primary stenting is an effective and reliable approach for complex plaques in stenoses. Patency of the arterial segment with a smooth lumen can be created without the risk of acute complications such as distal embolization, dissection, or occlusion.

Key words: Stents and prostheses—Stenoses—Arteries, aorta and iliac—Complex plaques—Transluminal angioplasty

Stent placement has become an established revascularization technique in aortoiliac arterial occlusive disease since the reporting of unsatisfactory long-term patency rates following percutaneous transluminal angioplasty (PTA) for irregular, eccentric, long, and ulcerated stenoses and occlusions [1–4]. Lesion type is an important factor influencing technical and follow-up results. The so-called complex atherosclerotic lesions—eccentric, calcified, and ulcerated plaques and dissections—are major factors decreasing the technical and follow-up success of iliac PTA [3–5].

Primary stenting in iliac arteries is said to be physiologically more effective in correcting arterial obliterative lesions, providing a smooth surface and preventing intimal tear, abrupt vessel closure, and distal embolization [5–8].

We report our results with primary stenting for complex atherosclerotic plaques in aortic and iliac stenoses.

Materials and Methods

Between November 1993 and July 1997 we performed a total of 121 aortoiliac PTA procedures including 49 primary or secondary stentings in 44 cases. Complex plaque morphology constituted our criteria in stenoses for primary stenting. All lesions treated were stenoses; no complete occlusion was included in this study. Stenotic segments were secondarily stented in cases with complications or an inadequate result following balloon angioplasty. In the same period we performed primary stent placement in 19 patients (Table 1) with 22 severe stenotic segments that included ulcerated plaques ($n = 17$), ulcerated plaques with focal aneurysms ($n = 8$), plaques with heavy calcification ($n = 3$), severely eccentric plaques ($n = 10$), plaques with overhanging edge ($n = 1$), and plaques with spontaneous dissection ($n = 2$). Seventeen of the stenotic segments presented more than one complex plaque morphology (Table 2). The length of the stenotic segments covered by stents varied between 1.0 cm and 5.0 cm (mean 2.2 ± 1.1 cm).

Eighteen men and one woman aged between 51 and 68 years (mean 61 ± 4 years) were treated. Clinically, 11 patients had a walking distance less than 200 m (Fontaine IIB), 7 patients had rest pain (Fontaine III), and one patient had trophic changes (Fontaine IV). Five of the patients with ulcerated plaques presented with "blue toe syndrome" due to microembolization. One lesion involving the aorta, 19 involving the common iliac artery, and two involving the external iliac artery were treated with a Palmaz stent (Johnson & Johnson Interventional Systems, Warren, NJ, USA) ($n = 19$), Wallstent (Schneider Europe, Zurich, Switzerland) ($n = 1$), Strecker stent (Meditech, Boston Scientific, Watertown, MA, USA) ($n = 1$), or Memotherm stent (Angiomed/Bard, Karlsruhe,

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Correspondence to: B. Önal, M.D.

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Table 1. Demographic data of the patients

Patients/conditions	*n*
Patients	19
Male	18 (95%)
Female	1 (5%)
Mean age	61 ± 4
Range	51–68
Associated medical conditions	
Hypertension	8 (40%)
Diabetes mellitus	3 (15%)
Cigarette smoking	18 (95%)

Germany) ($n = 1$). All patients had previously undergone angiography. One patient had two lesions in the same vessel and also superficial femoral artery occlusion. All other patients had patent superficial femoral arteries and at least one patent crural artery. One patient had bilateral stenosis of the external iliac arteries; another had bilateral stenosis of the common iliac arteries. Thirteen lesions were on the right and eight were on the left (Table 2). Atherosclerosis was the presumptive etiology of the occlusive process in all patients. Informed consent was obtained from all patients.

The technique of primary stenting included placement of a 5 Fr introducer sheath ipsilaterally, passage of the stenotic segment with a 0.035-inch Terumo guidewire, then replacement of the femoral sheath over the guidewire with a 7 or 8 Fr long stent-introducer sheath that was advanced retrogradely across the stenosis until its tip was proximal to the lesion, and subsequent placement of the stent over the guidewire to completely cover the stenotic segment. "Road map" and angiographic control via the contralateral approach were used for exact placement of the stent. The diameters of the stents were calculated from normal proximal or distal segments of the stenoses and the contralateral corresponding artery. Stent diameters and lengths varied between 8–10 mm and 10–60 mm, respectively.

After deployment, multiprojectional angiographic control of the stented segment was performed. A possible distal embolism was also excluded by femoropopliteal angiography during and after the procedure. Substantial relief of the stenosis with residual narrowing of 20% or less and no major morbidity was defined as technical success. Complete relief of or substantial improvement in presenting symptoms was defined as clinical success.

All patients were given an intravenous bolus of 5000 IU of heparin during stent placement. Medication after the procedure included acetylsalicylic acid (500 mg per day) and dipyridamole (225 mg per day) for 3–6 months.

The patients were evaluated clinically and by intravenous angiography the day after stent placement. The follow-up protocol included clinical examination, Doppler ultrasound, and intravenous or intraarterial angiography at 1–3, 6 and 12 months and then yearly unless the patient had any complaints. Intraarterial angiography was performed to ascertain regularity of the luminal contour as well as the patency of the stented segments, and to determine whether intimal hyperplasia was present in all cases at 1–3 months and in 13 cases at 12 months (Table 2). The clinical and angiographic follow-up period was 3–46 months (mean 19.6 months). Presence of a clear space between the lumen and the edge of the stent on angiograms was the criterion for intimal hyperplasia.

In the assessment of patency by Doppler ultrasound in the follow-up period, elevation of the peak systolic velocity across the stenosis of twice the prestenotic velocity or total occlusion within the stent was our criterion. Power Doppler ultrasound was also performed in the last two patients when it became available.

Results

In all cases, stents were deployed successfully. Stenotic segments were totally covered by stents. Immediate angiography after implantation revealed restoration of patency of the stented segments (Figs. 1, 2). Only in one case was the desired stent diameter not achieved. This was a 3-cm ulcerated and eccentric complex stenosis, causing 95% narrowing of the lumen that was treated with a 40-mm self-expandable Memotherm stent. The stenosis improved to 40% after stent placement. However, we did not perform a secondary intervention because the patient became clinically asymptomatic. Overall the technical success rate was 95% according to Society of Cardiovascular and Interventional Radiology (SCVIR) criteria [9].

The length of the arterial segment covered by stents varied between 1.0 cm and 5.0 cm (mean 3.0 ± 1.4 cm). Each lesion was covered by only one stent.

In stenoses with ulceration or focal aneurysm, immediate angiography after stenting revealed patency of the stenotic segment, but ulceration or aneurysm beneath the stent struts carried on filling with contrast material in most cases. In follow-up angiographies obtained 4–12 weeks after the procedure, ulcerations ($n = 9$) or focal aneurysms ($n = 3$) were found to be obliterated in all cases (Fig. 3).

No major or minor complications such as hematoma, pseudoaneurysm or arteriovenous fistula formation at the puncture site, or traumatic dissection, arterial rupture, stent misplacement, or migration at the angioplasty site occurred. We also did not observe any distal embolization during or after the procedure. The only early stent complication was subacute occlusion of the stented segments several days after the procedure in the case with multiple complex lesions of the iliac artery and additional ipsilateral superficial femoral artery occlusion treated with two Palmaz stents. We believe that poor distal runoff was the reason for this occlusive complication. The patient was referred for vascular surgery. Neither excessive intimal hyperplasia nor significant restenosis occurred in other cases. In 13 patients who had 12 months of angiographic follow-up, intraarterial angiograms were re-evaluated to analyze the thickness of intimal proliferation within the stents. All stented segments had visible intimal proliferation causing restenosis of less than 20%, which is hemodynamically insignificant.

All other stented segments were patent in the follow-up period of 3–46 months. Patency assessment was based on Doppler ultrasonography and arteriographic appearances. Cumulative primary patency rate was 94.7% ± 5.1% over 12 months (Table 3).

Clinical examination at 1–3 months after stent implantation showed improvement of clinical stage from Fontaine IV, III, or IIB to I (clinical success) in all cases but the occluded

Table 2. Summary of cases

Patient no.	Lesion location	Stage Fontaine		Extent of stenoses (%)		Indication for stent placement	Follow-up (months)
		Before	After	Before	After		
1	R CIA	III	I	95	0	a,d	46
2	R CIA	IV	I	90	0	c	36
3	L CIA	IIB	I	85	0	a,d	34
4	I aorta	IIB	I	95	0	a,c	34
5	R CIA	IIB	I	85	0	a	28
6	R CIA	IIB	I	80	0	c,d,e	25
7	R CIA	IIB	I	85	0	a,d	25
8	L CIA	III	I	90	0	a,c	25
9	L CIA	IIB	I	70	0	a,d	21
10	L CIA	IIB	I	70	0	a	18
11	R CIA	IIB	I	90	0	c,e	16
	L CIA			90	0	a,d	16
12	R CIA	III	III	85	occ	a,c	1
	R CIA			85	occ	a,c	1
13	L CIA	III	I	70	0	a,b,d	14
14	R CIA	IIB	I	80	0	a	14
15	R CIA	III	I	95	0	b,c	9
16	L EIA	III	I	99	0	c	8
	R EIA			95	0	a,d	8
17	L CIA	III	I	95	0	a,f	7
18	R CIA	IIB	I	85	0	a,b	7
19	R CIA	IIB	I	95	40	a,c	3

R = right; L = left; CIA = common iliac artery; EIA = external iliac artery; I = infrarenal; a = ulcerated plaque; b = calcified plaque; c = eccentric plaque; d = focal aneurysmal dilatation; e = spontaneous dissection; f = overhanging edge; occ = occluded.

one. This remained unchanged in the follow-up examinations (Table 2). The patients presenting with "blue toe syndrome" were also cured and became clinically stable without any complaints after stent placement in the follow-up period.

Palmaz stents were deployed in the majority of cases and the number of other stents was not significant for comparison.

Discussion

Balloon angioplasty remains the gold standard of percutaneous treatment in aortoiliac stenoses [10]. Becker et al. [4] analysed 2679 procedures with an average technical success of 92%, a 2-year patency of 81%, and a 5-year patency of 72%.

Although these results are very satisfactory, complications and limitations associated with PTA made interventional radiologists search for new approaches to provide patency of the diseased vessel with smooth contours [1, 2, 11]. Beginning with their first applications by Dotter, endovascular metallic stents have been widely used in the treatment of aortoiliac occlusive disease [1, 2, 11].

In addition to the limitations and complications of PTA, lesions that respond poorly to PTA, such as complex calcified or eccentric stenoses, plaques with ulceration or aneurysm formation, long segment stenoses with an irregular surface, and chronic occlusions, are an indication for stent placement [5, 8, 12, 13]. Our cases included these poorly responding stenoses due to complex atherosclerotic plaques but excluded chronic occlusions.

Because lesion morphology influences the technical and follow-up results, preselection of lesions is necessary to obtain optimal results by iliac PTA [13]. It has been shown that there is a direct relationship between the degree of vascular calcification and the extent of injury caused by PTA. Waller et al. [14] suggested that vessels with heavy calcification were most susceptible to PTA-induced injury while moderately calcified vessels were the most responsive. In eccentric lesions, balloon dilatation results in stretching of the relatively uninvolved portion of vessel wall instead of the stenosing plaque [15]. Stents have the ability to concentrically dilate an eccentric lesion in an iliac artery by distributing the dilating force equally around the entire circumference [12]. Plaques with ulceration or focal aneurysm are accepted to be a potential source of distal embolization during PTA. Treatment by stents provides a smooth arterial wall and thrombosis within the aneurysm or ulcerated part of the plaque, reducing the blood flow in the lesion [16]. Since all stenotic lesions in our series had complex plaque morphology, demonstration of regularity of the luminal contour after stenting was significant in addition to patency. Contour regularity is a dynamic process, especially in ulcerated plaques or plaques with focal aneurysms after stenting. That is why intraarterial angiography was preferred (even though it is an invasive procedure) at 1–3, 12, and 24 months.

Stenting of iliac artery lesions without prior balloon angioplasty has been shown to achieve a better physiological result and to improve long-term patency [5, 6].

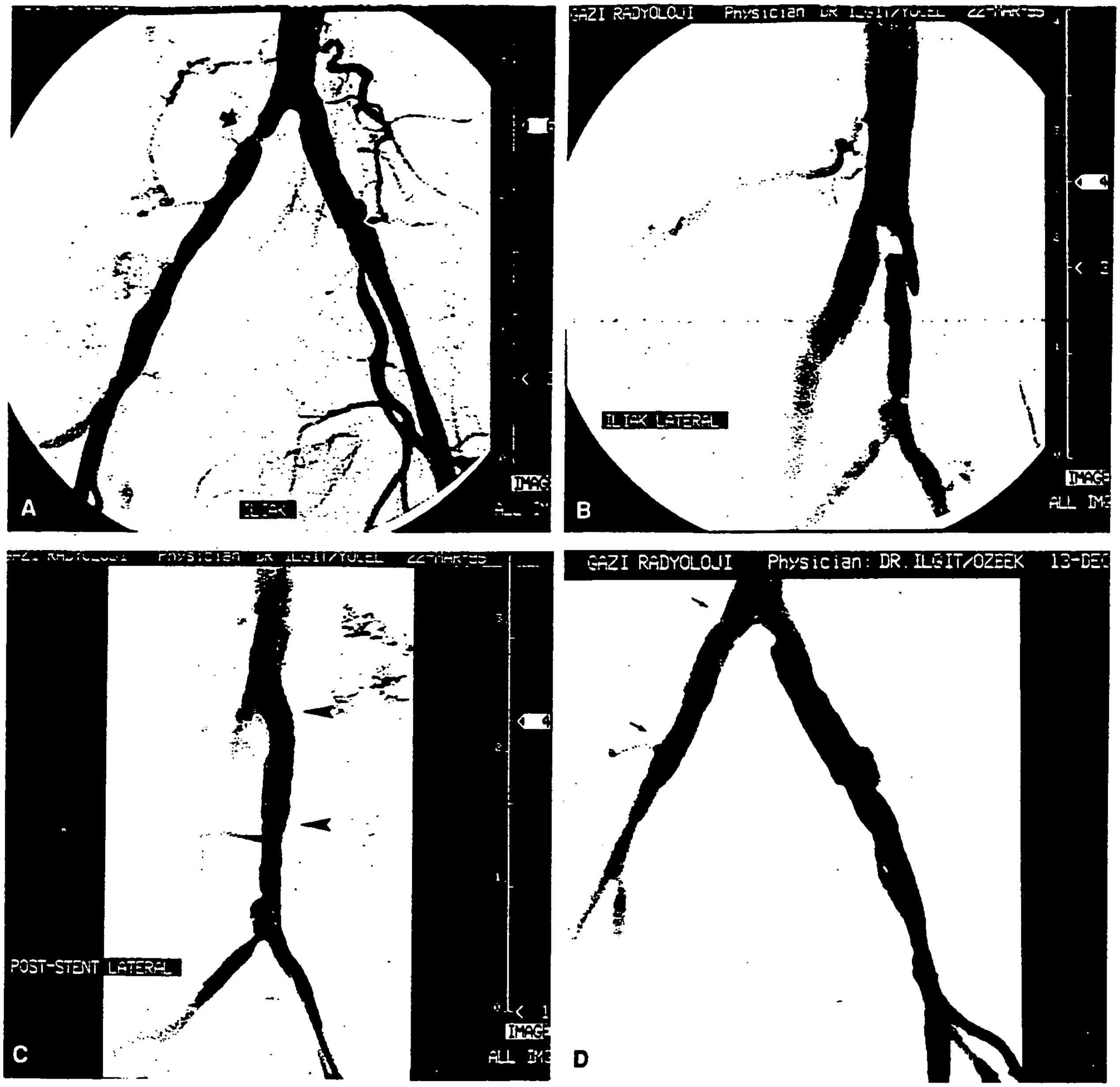

Fig. 1. *Case 6.* **A** Angiogram performed in posteroanterior projection shows a subtle stenosis of the right common iliac artery (arrow). **B** Angiogram obtained in lateral projection reveals a complex plaque that shows spontaneous dissection and eccentricity causing 80% narrowing of the arterial lumen. **C** Immediately after primary stenting there is patency of the stented segment with smooth contours (arrowheads). **D** Follow-up angiography at 9 months reveals patency of the stented segment (arrows).

Richter et al. [5] reported a cumulative 4-year patency rate of 94% for the stent group and 69% for the PTA group, in a randomized trial that compared the results of conventional PTA and primary stenting in iliac artery occlusive disease. As the technical aspects of iliac stent placement have evolved over the past few years, primary stent placement without preliminary balloon dilatation can be safely performed in the majority of cases [17]. There are some other reports suggesting that PTA before stent application is not always necessary and that it is possible to implant the stent during the first balloon inflation [18]. However, the number of these primarily stented cases comprise only a small part of the series [19].

Vorwerk et al. [6, 20] introduced primary stenting for iliac artery occlusions. Because the percutaneous treatment of chronic iliac artery occlusions is controversial, a primary patency rate of 78% and secondary patency rate of 88% for 3 years, respectively, is encouraging [20].

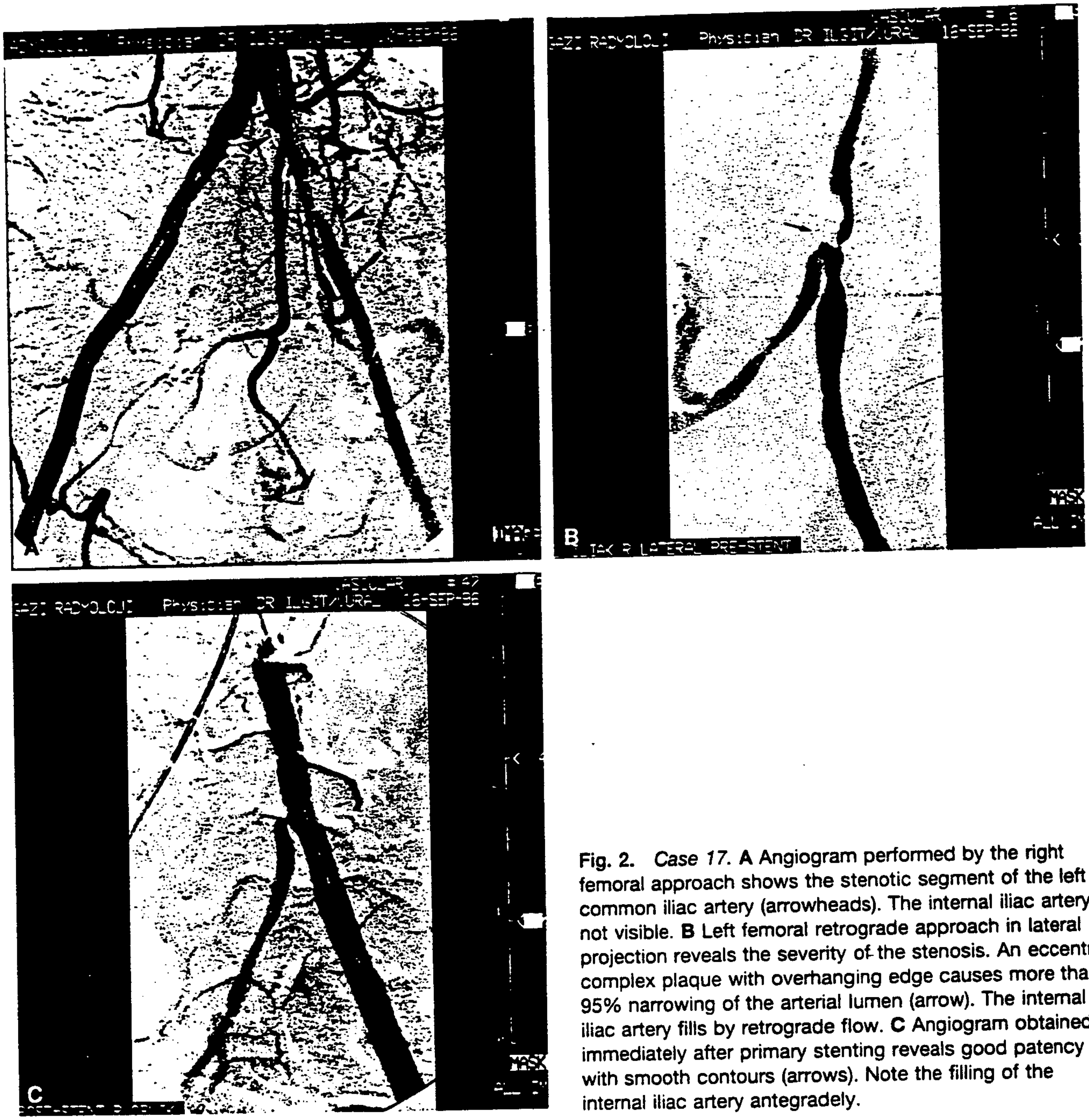

Fig. 2. *Case 17.* **A** Angiogram performed by the right femoral approach shows the stenotic segment of the left common iliac artery (arrowheads). The internal iliac artery is not visible. **B** Left femoral retrograde approach in lateral projection reveals the severity of the stenosis. An eccentric complex plaque with overhanging edge causes more than 95% narrowing of the arterial lumen (arrow). The internal iliac artery fills by retrograde flow. **C** Angiogram obtained immediately after primary stenting reveals good patency with smooth contours (arrows). Note the filling of the internal iliac artery antegradely.

Other studies concerning arterial segments in which distal embolization is a risk suggest primary stent placement as the treatment of choice. Kumar et al. [21] introduced primary stent placement in occlusive subclavian artery disease. They declared the technique to be simple, safe, and effectively managed with excellent success and minimal morbidity. Percutaneous treatment of carotid stenoses is also another field where primary stent placement plays an important role. To reduce the 20% rate of restenosis after PTA and reduce the rate of embolization during dilatation, primary stent placement was preferred [22].

Technically, it may be necessary to predilate the stenosis with an undersized 3–5-mm balloon to effect passage of the stent-catheter assembly [6, 22, 23]. None of the stenoses in our cases required predilatation with an undersized balloon, as the stenotic segment was traversed with a 7 or 8 Fr long dilator-introducer sheath assembly. In cases with severe stenoses, sheath introduction resulted in coaxial dilatation of the stented segment.

It is suggested that caution should be exercised with heavily calcified lesions, since the preselected diameter might occasionally not be achieved by primary stenting [17]. Fortunately, we did not find underdilatation of the stented segment with heavy calcification in our cases.

The only attempt that resulted in underdilatation was the primary stenting of an ulcerated and eccentric complex ste-

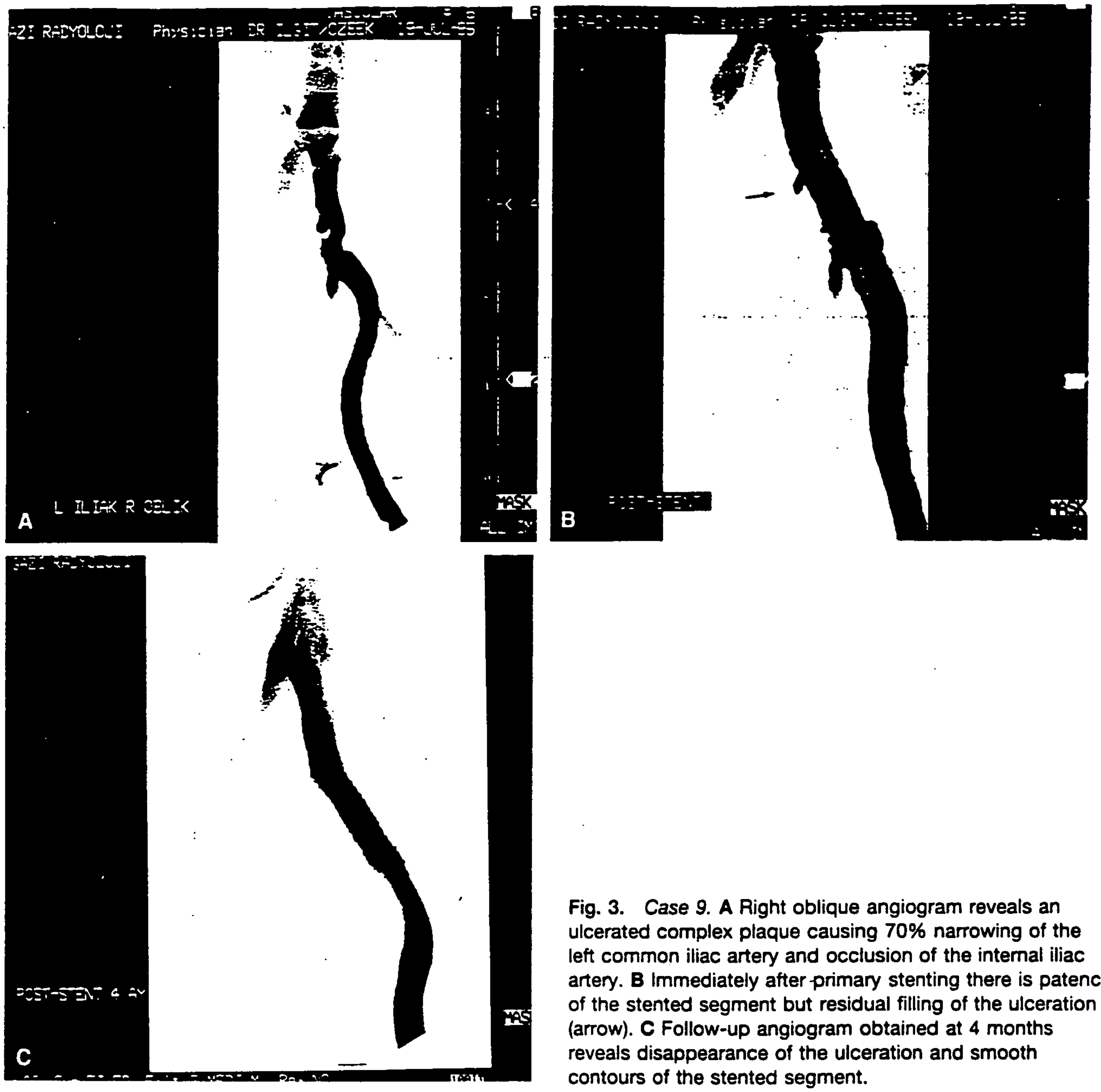

Fig. 3. *Case 9.* **A** Right oblique angiogram reveals an ulcerated complex plaque causing 70% narrowing of the left common iliac artery and occlusion of the internal iliac artery. **B** Immediately after primary stenting there is patency of the stented segment but residual filling of the ulceration (arrow). **C** Follow-up angiogram obtained at 4 months reveals disappearance of the ulceration and smooth contours of the stented segment.

notic segment with a Memotherm stent. The interrupted mesh pattern of the stent that results in internally protruding sharp edges discouraged us from a secondary intervention [24]. The patient was asymptomatic and the stenosis improved to 40%; we did not perform a secondary intervention.

Treatment of plaques with ulceration or focal aneurysm by noncovered stents has been suggested unless the aneurysm has a fusiform shape. This is because insufficient closure could occur in fusiform aneurysms if the noncovered stent had a large segment not in close contact with the vascular wall [16]. In all our cases with ulcerated plaques or plaques with focal aneurysm we achieved smooth contours of the stented segments and no distal embolization occurred (it was mentioned previously that stent filaments remaining within the arterial lumen might have been a source of emboli [16]).

The outcome of stent implantation is influenced by lesion length, location of the stenosis, and distal runoff status. The presence of more than one of these factors increases the chance of stent failure [6, 8, 23], as happened in our only case with multiple complex lesions of the common iliac artery and superficial femoral artery occlusion.

Although different stent types have similar patency rates in iliac stenoses [23, 25], we believe that balloon-expandable stents are more likely to achieve preselected diameters in aortoiliac stenotic lesions due to complex plaques. Also,

Table 3. Results of Kaplan–Meier analysis for primary patency

Follow-up (months)	Total number of patients	Events	Cumulative patency ± SE (%)
0	19	0	100 ± 0.0
1	19	1	94.7 ± 5.1
3	18	0	94.7 ± 5.1
6	17	0	94.7 ± 5.1
12	13	0	94.7 ± 5.1
24	8	0	94.7 ± 5.1
36	2	0	94.7 ± 5.1

their uninterrupted mesh pattern increases the radial force when combined with balloon inflation. These factors enable the Palmaz stent to compress a complex plaque with a high radial strength, especially in calcified stenoses.

It is obvious that stent placement is not necessary in all cases, as PTA has reasonable results and a good cost-benefit ratio [26]. However, predilatation of stenotic segments that will probably be stented increases the cost of the percutaneous intervention. Primary stenting decreases this extra cost, avoiding the waste of an angioplasty balloon.

Stenoses with complex plaque morphology that are not amenable to balloon angioplasty alone because of a high risk of complication and low patency rates constitute the indication for primary stenting. We think that primary stenting is an effective and reliable approach for complex atherosclerotic plaques in aortic and iliac stenoses. Patency of the arterial segment with a smooth lumen can be created without the risk of acute complications such as distal embolization, dissection, or occlusion.

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